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EXHIBIT 8

RESPONSE TO SMDA OF 1990

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

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DEVICE NAME: Pulpdent Seal-Rite™ UDMA

PREDICATE DEVICE: Pulpdent *Seal-Rite and Seal-Rite Low Viscosity*
Vivodent/Ivoclar Helioseal and HelioSeal-F
Kulzer Estiseal
Ultradent Ultra-Blend

DESCRIPTION AND INTENDED USE: *Pulpdent Seal-Rite™ UDMA* is a radiopaque, fluoride-releasing, visible light cure dental material for sealing the pits and fissures of teeth. It contains no Bisphenol A. It is supplied as a medium consistency paste, which flows readily from cusp to cusp and is easily distinguishable from enamel. *Pulpdent Seal-Rite™ UDMA* cures completely after light curing for 20 seconds. Various formulations (with and without color, with and without fluoride) will be offered to allow for the clinician's discretion and preference in different situations. *Pulpdent Seal-Rite™ UDMA* complies with ANSI/ADA Specification No. 39 for Pit and Fissure Sealants.

COMPARISON WITH PREDICATE PRODUCTS: *Pulpdent Seal-Rite™ UDMA* is substantially equivalent in composition and/or intended use to the above mentioned predicate products. Please see EXHIBIT 5 for the entire comparison.

SAFETY AND EFFECTIVENESS: According to the NIH Technology Assessment Conference on Effects and Side-Effects of Dental Restorative Materials, "General usage of these materials over about 20 years indicates a high benefit-to-risk ratio...both composites and glass ionomers are relatively trouble free. There is no evidence of short or long term risk...there is no suspicion of any problems after literally billions of procedures in the United States." Please see EXHIBIT 6 for the complete papers from the conference.